



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Walter ELGER et al. : Group Art Unit: 1617
Serial No.: 09/744,574 : Examiner: JIANG, Shaojia A.
Filed: 5 April 2001 :
For: USE OF BIOGENIC ESTROGEN SULFAMATES FOR HORMONE REPLACEMENT
THERAPY

APPEAL BRIEF

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal filed on May 24, 2005, please consider the following.

The attached check includes the fee as set forth under § 41.20(b)(2).

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

(i) REAL PARTY IN INTEREST

The real party in interest is Schering AG.

(ii) RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

There was a previous appeal, i.e., appeal no. 2003-2087, in this case where the currently appealed double patenting rejections were not decided on the merits. In that appeal however, 35 USC § 103 obviousness rejections were decided in favor of applicants over two references with similar disclosure on the question of whether a teaching of daily administrations renders the current claims obvious. The previous decision on this question by the Board is believed dispositive of the double patenting rejections on appeal here.

In the related proceedings appendix, for convenience, a copy of the Board decision discussed above is attached.

(iii) STATUS OF CLAIMS

Claims 9, 11, and 13-25 are pending in the present application. The final rejection dated February 24, 2005, erroneously identifies only claims 9, 11, and 13-17 as pending.

In preparation of this brief, applicants for the first time noticed a procedural error by the PTO in which additional claims 18-25 filed on May, 5, 2004, were not entered. Such error was not noticed before probably because the issues with respect to the claims are the same whether the additional claims are entered or not.

On May 5, 2004, applicants filed an amendment adding claims 18-25. The USPTO PAIR system in the file history section for 05-05-2004 lists "Workflow incoming amendment IFW," but the image file wrapper for the application does not have such amendment listed/scanned. In the evidence appendix are a copy of the amendment filed on May 5, 2004, a copy of the stamped postcard with the PTO acknowledging receipt of the amendment, a printout of the PAIR system's file history and of image file wrapper pages for this application. Applicants believe the issues on appeal over the rejected claims are also present in the claims that appear not to have been reviewed by the Examiner, and thus, request the continuation of this appeal with the consideration of all the claims as if they were all rejected.

Concurrently filed with this appeal brief is a paper to the USPTO pointing out the possibility that the claims filed on May 5, 2005, may not have been scanned, and therefore may not have been entered, with documentation identical to the papers in the evidence appendix.

Claims 9, 11, and 13-17 were rejected (probably would have been claims 9, 11, and 13-25), all of which claims are on appeal.

(iv) STATUS OF AMENDMENTS

No amendments were filed after final.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention is directed to a method of achieving hormone replacement therapy in a woman by intermittently orally administering an estrogen sulfamate to said woman. The intermittent administration is in intervals of 2 or 3 days for a dosage of 20-300

µg/day, 5-10 days for a dosage of 0.5-5.0 mg/day, or 20-40 days for a dosage of 2.0-20 mg/day. See specification on page 1, lines 1-3, and page 13, last 5 lines on the page, to page 14, first two lines on the page.

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds for rejections are under the judicially created doctrine of obviousness-type double patenting, i.e., whether claims 9, 11, and 13-17 are patentable over US 6,653,298.

(vii) ARGUMENT

The final rejection dated February 24, 2005, alleges that the claims are not patentable under the doctrine of obviousness-type double patenting over claims 2, 4-7, and 11-18 of US 6,653,298 since the “patent is deemed to encompass the instant claims.” The Office Action points to the claims and the specification of US 6,653,298.

However, the test for obviousness-type double patenting is not whether the entire patent over which the claims are rejected encompasses the claims. Rather, the test encompasses a two step inquiry, i.e., the first question in the analysis is: “Is the same invention being claimed twice?” and if the answer to this first question is no, which is admitted in the Office Action, then the second analysis question is: “Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent?” See *In re Vogel*, 422 F.2d 438, 164 USPQ 617 (CCPA 1970).

The answer to the second question has already been answered in the negative in this case on appeal over two references (WO 96/05216 and US 5,314,694), which posed the question of whether a teaching of daily administration renders the current claims obvious. The Board held that a teaching of daily administration did NOT render obvious the intermittent administration of the present claims. See the Board decision in this case mailed on March 25, 2004.


The claims of US 6,653,298 are directed to administrations of “no greater than 200 µg/day per 70 kg subject” (see independent claims 1-3) and “from 10 to 200 µg/day” (see dependent claims 4-6). Emphasis added. All the remaining claims in ‘298 are dependent on the three independent claims, i.e., claims 1-3, and do not further change or limit the dosage regimens. Thus, all of the reference’s claims at issue are directed to daily administrations which were previously held not to render obvious the intermittent administration of the present claims.

The Office Action points to the specification of ‘298 when making the rejection and alleges that the patent teaches weekly and monthly administrations. It is well settled law that the

patent disclosure over which the rejection is made may not be used as prior art in an obviousness-type double patenting rejection. In limited circumstances the specification may be looked at, for example, only as a dictionary to learn the meaning of terms used in a claim, but the rejection has to be over the claims of the patent and not over the disclosure. See *Vogel*, supra.

Accordingly, reversal of the rejection is mandated by law, and is respectfully and courteously requested.

Respectfully submitted,



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Attorney Docket No.: GULDE-26

Date: **August 24, 2005**

CH/AJZ/pdrK:\GULDE\26\Appeal Brief 2.doc

(viii) CLAIMS APPENDIX

9. A method according to claim 11, wherein the estrogen sulfamate is estrone sulfamate, estradiol sulfamate, estriol sulfamate, N-acylsulfamate of estrone, estradiol or estriol having an acyl chain of up to 7 C atoms or mixtures thereof.

11. A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 0.5-5.0 mg on each day when administered in intervals of 5-10 days.

13. A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 2.0-20 mg on each day when administered in intervals of 20-40 days.

14. A method according to claim 11, further comprising the administration of a gestagen.

15. A method according to claim 14, wherein the at least one gestagen is levonorgestrel, desogestrel, norethisterone, medroxyprogesterone acetate, megestrol, cyproterone acetate, chlormadinone acetate, dienogest, drospirenone or a mixture thereof.

16. A method according to claim 14, wherein the at least one gestagen is continuously administered.

17. A method according to claim 16, wherein the continuous administration is in the form of an implant, in the form of an intrauterine release system or in the form of a combination thereof.

18. A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 20-300 µg/day in intervals of 2 or 3 days; 0.5-5.0 mg/day in intervals of 5-10 days; or 2.0-20 mg/day in intervals of 20-40 days.

19. A method according to claim 18, wherein the estrogen sulfamate is estrone sulfamate, estradiol sulfamate, estriol sulfamate, N-acylsulfamate of estrone, estradiol or estriol having an acyl chain of up to 7 C atoms or mixtures thereof.

20. A method according to claim 18, wherein the intermittent oral administration is carried out at an interval of 2 to 40 days between administrations.

21. A method according to claim 18, wherein the intermittent oral administration is carried out at an interval of 2 to 3 days between administrations.

22. A method according to claim 18, further comprising the administration of a gestagen.

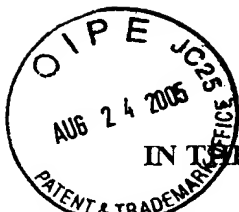
23. A method according to claim 22, wherein the at least one gestagen is levonorgestrel, desogestrel, norethisterone, medroxyprogesterone acetate, megestrol, cyproterone acetate, , chlormadinone acetate, dienogest, drospirenone or a mixture thereof.

24. A method according to claim 22, wherein the at least one gestagen is continuously administered.

25. A method according to claim 24, wherein the continuous administration is in the form of an implant, in the form of an intrauterine release system or in the form of a combination thereof.

(ix) EVIDENCE APPENDIX

- 1) Copy of Amendment filed on May 5, 2004.
- 2) Copy of the stamped postcard with the PTO acknowledging receipt of the amendment filed on May 5, 2004.
- 3) Printout of the USPTO PAIR system file history section for this application listing "Workflow incoming amendment IFW" for 05-05-2004.
- 4) Printout of the USPTO PAIR system image file wrapper section for this application listing nothing for 05-05-2004.



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Group Art Unit: 1617

Serial No.: 09/744,574

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Examiner: M. Bahar

Filed: 5 April 2001

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For: USE OF BIOGENIC ESTROGEN SULFAMATES FOR HORMONE REPLACEMENT
THERAPY

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

Please enter the following amendment.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-8. (Cancelled)

9. (Previously Presented) A method according to claim 11, wherein the estrogen sulfamate is estrone sulfamate, estradiol sulfamate, estriol sulfamate, N-acylsulfamate of estrone, estradiol or estriol having an acyl chain of up to 7 C atoms or mixtures thereof.

10. (Cancelled)

11. (Previously Presented) A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 0.5-5.0 mg on each day when administered in intervals of 5-10 days.

12. (Cancelled)

13. (Previously Presented) A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 2.0-20 mg on each day when administered in intervals of 20-40 days.

14. (Previously Presented) A method according to claim 11, further comprising the administration of a gestagen.

15. (Previously Presented) A method according to claim 14, wherein the at least one gestagen is levonorgestrel, desogestrel, norethisterone, medroxyprogesterone acetate, megestrol, cyproterone acetate, chlormadinone acetate, dienogest, drospirenone or a mixture thereof.

16. (Previously Presented) A method according to claim 14, wherein the at least one gestagen is continuously administered.

17. (Previously Presented) A method according to claim 16, wherein the continuous administration is in the form of an implant, in the form of an intrauterine release system or in the form of a combination thereof.
18. (New) A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 20-300 µg/day in intervals of 2 or 3 days; 0.5-5.0 mg/day in intervals of 5-10 days; or 2.0-20 mg/day in intervals of 20-40 days.
19. (New) A method according to claim 18, wherein the estrogen sulfamate is estrone sulfamate, estradiol sulfamate, estriol sulfamate, N-acylsulfamate of estrone, estradiol or estriol having an acyl chain of up to 7 C atoms or mixtures thereof.
20. (New) A method according to claim 18, wherein the intermittent oral administration is carried out at an interval of 2 to 40 days between administrations.
21. (New) A method according to claim 18, wherein the intermittent oral administration is carried out at an interval of 2 to 3 days between administrations.
22. (New) A method according to claim 18, further comprising the administration of a gestagen.
23. (New) A method according to claim 22, wherein the at least one gestagen is levonorgestrel, desogestrel, norethisterone, medroxyprogesterone acetate, megestrol, cyproterone acetate, , chlormadinone acetate, dienogest, drospirenone or a mixture thereof.
24. (New) A method according to claim 22, wherein the at least one gestagen is continuously administered.
25. (New) A method according to claim 24, wherein the continuous administration is in the form of an implant, in the form of an intrauterine release system or in the form of a combination thereof.

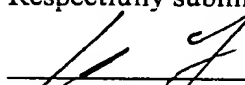
REMARKS

On October 15, 2003, applicants filed an RCE to have the appeal process terminated, and requested entry of amendments not entered after final. The Board of Appeals on March 25, 2004, nevertheless made a decision on the merits that was favorable to applicants on the unamended version of the claims. This amendment recaptures material previously amended out of the claims but now allowed by the Board.

There is also an outstanding double patenting issue. The Board affirmed the double patenting rejection because applicants did not provide arguments in the Appeal Brief. For the same reasons that the claims were held not obvious by the Board, the claims are also not obvious under the obviousness-type double patenting issue. Additionally, the assignees are not the same on the current application and on the now issued patent over which the rejection is made.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Attorney Docket No.: GULDE-26

Date: May 5, 2004

CH/AJZ/pdr



SERIAL NO. 09/744,574

DOCKET NO. GULDE-26

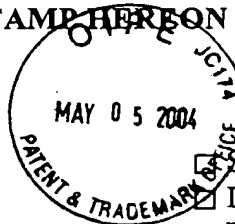
FILED: April 5, 2001

APPLICANT(S) Walter ELGER et al.

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☐ PRIORITY DOCUMENT(S)
☐ VERIFIED STATEMENT(S) UNDER 37 C.F.R. 1.9 & 1.27
☐ CONTINUATION PROSECUTION APPLICATION (CPA)



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OTHER Preliminary Amendment

Initials: CH/pdr

Date Filed: May 5, 2004

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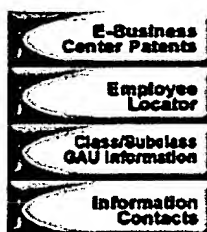
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Search results for application number:09/744,574			
Application Number:	09/744,574	Customer Number:	23599
Filing or 371(c) Date:	04-05-2001	Status:	Notice of Appeal Filed
Application Type:	Utility	Status Date:	06-01-2005
Examiner Name:	JIANG, SHAOJIA A	Location:	ELECTRONIC
Group Art Unit:	1617	Location Date:	-
Confirmation Number:	1528	Earliest Publication No:	-
Attorney Docket Number:	JENA-6	Earliest Publication Date:	-
Class/ Sub-Class:	514/310	Patent Number:	-
First Named Inventor:	Walter Elger, Berlin, (DE)	Issue Date of Patent:	-
Title Of Invention:	Use of biogenic estrogen sulfamates for hormone replacement therapy		

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File History	
Date	Contents Description
05-24-2005	Notice of Appeal Filed
02-24-2005	Mail Final Rejection (PTOL - 326)
02-22-2005	Final Rejection
12-04-2004	Date Forwarded to Examiner
11-23-2004	Response after Non-Final Action
11-23-2004	Workflow incoming amendment IFW
10-04-2004	Mail Non-Final Rejection
09-30-2004	Non-Final Rejection
07-27-2004	Date Forwarded to Examiner
07-23-2004	Response after Non-Final Action
04-05-2001	Oath or Declaration Filed (Including Supplemental)
01-26-2001	Preliminary Amendment
07-23-2004	Workflow incoming amendment IFW
06-30-2004	Mail Notice of Informal or Non-Responsive RCE Amendment
06-29-2004	Notice of Informal or Non-Responsive RCE Amendment.
06-29-2004	Date Forwarded to Examiner
06-29-2004	Date Forwarded to Examiner
10-15-2003	Request for Continued Examination (RCE)
06-29-2004	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)
06-16-2004	Case Docketed to Examiner in GAU
05-05-2004	Workflow incoming amendment IFW
04-02-2004	Case Docketed to Examiner in GAU

03-25-2004	Mail BPAI Decision on Appeal - Affirmed
03-25-2004	BPAI Decision - Examiner Affirmed
10-15-2003	Workflow - Request for RCE - Begin
09-24-2003	Docketing Notice Mailed to Appellant
09-24-2003	Assignment of Appeal Number
09-17-2003	Appeal Awaiting BPAI Docketing
09-17-2003	Mail Miscellaneous Communication to Applicant
09-16-2003	Miscellaneous Communication to Applicant - No Action Count
09-09-2003	Date Forwarded to Examiner
08-13-2003	Reply Brief Filed
07-02-2003	Mail Examiner's Answer
06-30-2003	Examiner's Answer to Appeal Brief
04-23-2003	Date Forwarded to Examiner
04-21-2003	Amendment/Argument after Notice of Appeal
04-23-2003	Date Forwarded to Examiner
04-21-2003	Appeal Brief Filed
04-21-2003	Request for Extension of Time - Granted
12-04-2002	Mail Advisory Action (PTOL - 303)
12-02-2002	Advisory Action (PTOL-303)
11-19-2002	Date Forwarded to Examiner
11-14-2002	Amendment/Argument after Notice of Appeal
11-14-2002	Notice of Appeal Filed
11-14-2002	Request for Extension of Time - Granted
05-14-2002	Mail Final Rejection (PTOL - 326)
05-03-2002	Final Rejection
02-22-2002	Date Forwarded to Examiner
01-22-2002	Response after Non-Final Action
01-22-2002	Request for Extension of Time - Granted
06-21-2001	Information Disclosure Statement (IDS) Filed
06-20-2001	Mail Non-Final Rejection
06-18-2001	Non-Final Rejection
05-29-2001	Case Docketed to Examiner in GAU
04-05-2001	Preliminary Amendment
05-10-2001	Application Dispatched from OIPE
05-09-2001	IFW Scan & PACR Auto Security Review
04-19-2001	Released to OIPE
04-20-2001	Notice of DO/EO Acceptance Mailed
04-05-2001	Applicant 371 Filing Paper Received
03-05-2001	Notice of DO/EO Missing Requirements Mailed
02-16-2001	371 Application Preexamination Docketing
02-02-2001	371 Application Preexamination Docketing
01-26-2001	Receipt of 371 Request
02-02-2001	Correspondence Address Change
04-05-2001	Initial Exam Team nn

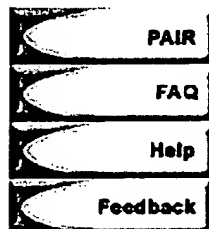
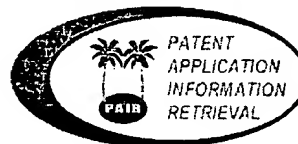
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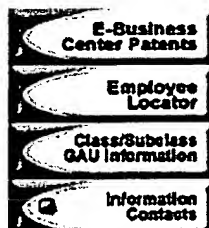


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NEW *Changes to*

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Mail Room Date	Document Description	Document Category	Page Count
05/24/2005	Notice of Appeal Filed	PROSECUTION	1
02/24/2005	Search information including classification, databases and other search related notes	PROSECUTION	1
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11/23/2004	Applicant Arguments or Remarks Made in an Amendment	PROSECUTION	1
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01/26/2001	<u>Issue Information including classification, examiner, name, claim, renumbering, etc.</u>	PROSECUTION	1
01/26/2001	<u>Authorization from Applicant to treat all replies as incorporating Extension of Time, and charge all fees to a deposit account</u>	PROSECUTION	2
01/26/2001	<u>Preliminary Amendment</u>	PROSECUTION	1
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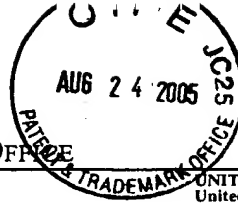
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(x) RELATED PROCEEDINGS APPENDIX

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,574	04/05/2001	Walter Elger	JENA-6	GULDE-0026 ⁵²⁸
23599	7590	03/25/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			BAHAR, MOJDEH	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AFFIRMED

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03/29/04
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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

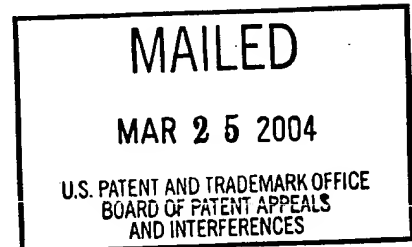
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte WALTER ELGER, PEKKA LAHTENMAKI,
MATTI LEHTINEN, GUDRUN REDDERSEN,
HOLGER ZIMMERMANN, MICHAEL OETTEL, and
SIGFRID SCHWARZ

Appeal No. 2003-2087
Application No. 09/744,574

ON BRIEF



Before WINTERS, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8-17, all of the claims remaining. Claim 8 is representative and reads as follows:

8. A method of achieving hormone replacement therapy in a woman comprising intermittently orally administering an estrogen sulfamate at a dosage of 20-300 µg/day in intervals of 2 or 3 days; 0.5-5.0 mg/day in intervals of 5-10 days; or 2.0-20 mg/day in intervals of 20-40 days.



The examiner relies on the following references:

Gale et al. (Gale)	5,314,694	May 24, 1994
Siemann	WO 96/05216	Feb. 22, 1996

Claims 8-17 stand provisionally rejected for obviousness-type double patenting over claims 23 and 24 of application 09/755,429. Claims 8-17 also stand rejected under 35 U.S.C. § 103 as obvious in view of Siemann and Gale.

We affirm the double patenting rejection and reverse the obviousness rejection.

Background

The specification discloses the use of "biogenic estrogen sulfamates" such as estradiol sulfamate in hormone replacement therapy. See, e.g., pages 1 and 11. The estrogen sulfamates are disclosed to be prodrugs that are converted into the bioactive species by cleavage of the sulfamate group. Administration of the sulfamate prodrug is disclosed to have the advantage that "[b]y slow release from the sulfamate prod[r]ug in humans according to the invention, very uniform, exactly defined levels of natural estrogens can be built up in the blood." Page 13. "Slow release of natural estrogens, in connection with a high oral bio-availability of the steroid portion of the administered estradiol sulfamate according to the invention, allows use at larger intervals." Id.

Discussion

The claims are directed to a method of achieving hormone replacement therapy by intermittently (i.e., less often than daily) administering an estrogen

sulfamate, at specified dosages. The examiner rejected the claims for obviousness and for obviousness-type double patenting.

1. Double patenting

The examiner provisionally rejected all of the pending claims under the doctrine of obviousness-type double patenting over claims 23 and 24 of application 09/755,429.

Appellants argue that it would be "premature to determine whether a terminal disclaimer is necessary to overcome the [rejection] as no allowable subject matter has been identified in at least the present application. Applicants plan to address this issue after allowable subject matter is identified." Reply Brief, page 1.

We will affirm the rejection. The practice of making "provisional" double-patenting rejections based on pending applications has been sanctioned by the courts and by this board. See In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966); Ex parte Karol, 8 USPQ2d 1771 (Bd. Pat. App. Int. 1988). Such rejections are proper even when allowable subject matter has not been identified in one, or even both, of the conflicting applications. See, e.g., Karol, 8 USPQ2d at 1773-74 (claims in application on appeal stood rejected for obviousness-type double patenting over claims in copending application; rejection affirmed even though both claims on appeal and claims in copending application also stood rejected for obviousness).

Thus, the rejection is not premature and the propriety of the rejection is an issue in this appeal. In addition, the '429 application has now issued (as U.S. Patent 6,653,298), so the rejection is no longer provisional.

Since the rejection is properly before us and Appellants have not disputed its merits, we affirm it.

2. Obviousness

The examiner also rejected claims 8-17 as obvious in view of Siemann and Gale. The examiner characterized Siemann as "teach[ing] novel estra-1,3,5,(10)-triene amidosulphamates . . . [and] further teach[ing] employing these compounds in compositions and methods for hormone replacement therapy." Examiner's Answer, page 4. The examiner also characterizes Siemann as teaching a dosage of "10 microgram[s] of estradiol, ethinyl-estradiol and estriol per animal per day." *Id.* The examiner relied on Gale only for its teaching of administering estrogen in combination with a gestagen, a limitation that is relevant only to certain dependent claims. With regard to the "intermittent dosing" limitation of claim 8, the examiner argued that "[i]ntermittent administration instead of daily administration . . . is an optimization of regimen, within the purview of the Skilled Artisan." Examiner's Answer, page 6.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A proper § 103 analysis requires "a searching comparison of the claimed

invention – including all its limitations – with the teaching of the prior art.” In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

In this case, the examiner has not adequately shown that the prior art would have suggested the method defined by claim 8 to those of ordinary skill in the art. The examiner's rejection has several flaws. First, it relies on a reference that is entirely in German except for an English-language abstract. The abstract does not support the examiner's characterization of the reference.

However, Appellants appear to agree that Siemann “teaches the daily administration of 10 micrograms per day of an estradiol, ethinyl estradiol, and estriol while also disclosing a generic formula that encompasses estriol-3-sulphamate.” Appeal Brief, page 3. We will therefore accept the examiner's characterization of the reference.

We nonetheless conclude that Siemann does not support a prima facie case of obviousness, because the examiner has not adequately shown that it suggests the intermittent dosing limitation recited in the claims. According to the examiner, Siemann discloses daily administration, to rats, of 10 µg of an estrogen sulfamate compound. The examiner has not adequately explained how this disclosure would have suggested to those skilled in the art the dosage amounts and schedules recited in claim 8; specifically, 20-300 µg/day every 2-3 days, 0.5-5.0 mg/day every 5-10 days, or 2.0-20 mg/day every 20-40 days.

The examiner's argument—that these dosages are simply “an optimization of regimen”—is not sufficient to support a prima facie case under § 103. It is true that, given a variable that is known to affect the results of a process, disclosure of

an optimal value for that variable is generally not considered nonobvious. See, e.g., In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980).

In this case, however, the examiner has provided no evidence to show that those skilled in the art would have expected that an "optimal" dosage regimen using estrogen-sulfamates in HRT would have included administration less often than once per day. Siemann apparently administered the hormones on a daily basis. Gale, the examiner's secondary reference, discloses "continuous" co-administration of drugs. See column 5, line 8. The instant specification discloses that natural estrogens are quickly eliminated from circulation (page 3), and the examiner has pointed to nothing to show that those skilled in the art would have expected a different result with estrogen-sulfamates.

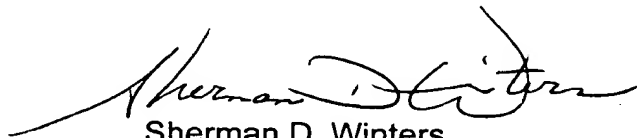
The examiner has not shown that those skilled in the art would have been led to "optimize" a hormone replacement therapy regimen by administering estrogen sulfamates less often than once per day. Therefore, the examiner has not shown that the claimed method would have been prima facie obvious based on the prior art. The rejection under 35 U.S.C. § 103 is reversed.

Summary

We reverse the rejection under 35 U.S.C. § 103 but affirm the rejection for obviousness-type double patenting.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



Sherman D. Winters
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge

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